

**Notice of Allowability**

Application No.

10/632,393

Applicant(s)

MCKEOWN ET AL.

Examiner

Art Unit

Pablo Whaley

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the After Final amendment filed 12/21/06.
2. ☒ The allowed claim(s) is/are 51,52 and 62-69.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 2/12/2007.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
REMI YUCEL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended to remove the term "substantially" (claim 51, line 7) as follows:

Claim 51. A method of performing a primer extension reaction to identify variant nucleotides of target nucleic acids using chain terminators, comprising:

obtaining an amplicon having a sequence generated from a target nucleic acid and a sequence generated from a first strand amplification primer, by amplifying a target nucleic acid having a nucleotide sequence containing a variant nucleotide flanked by an invariant nucleotide, wherein the first strand amplification primer employed to generate the sequence from the first strand amplification primer comprises a 5' tag ~~[substantially]~~ incapable of hybridizing to the target nucleic acid under amplification conditions, and wherein the 5' tag contains the same nucleotide bases in sequence as the variant nucleotide and the invariant nucleotide of the target nucleic acid,

employing the amplicon in a primer extension reaction wherein the identity of the variant nucleotide in the sequence generated from the target nucleic acid is determined by hybridizing a first identification primer immediately adjacent to the variant nucleotide in the sequence generated from the target nucleic acid;

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hybridizing a second identification primer immediately adjacent to the variant nucleotide in the sequence generated from the 5' tag of the first strand amplification primer;

extending the first and the second identification primers in the presence of two or more chain terminators and a polymerizing agent; and

determining the identity of the variant nucleotide generated from the target nucleic acid by comparing extension product of the first identification primer and extension product of the second identification primer to identify the variant nucleotide of the target nucleic acid.

#### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

#### *TERMINAL DISCLAIMER*

The terminal disclaimer, filed 12/21/2006, has been approved 2/2/2007.

#### *PRIOR ART*

The closest prior art of Pastinen et al. (Clinical Chemistry, 1996, 42:9, p.1391-1397) and Van Ness et al. (Pub. Pat. US2004/0038256, Filed: Oct. 1, 2001) do not teach or fairly suggest the amplification of a target nucleic acid containing a variant nucleotide flanked by an invariant nucleotide, wherein the first strand amplification primer employed to generate the sequence from the first strand amplification primer comprises a 5' tag incapable of hybridizing to the target nucleic acid under amplification conditions, and wherein the 5' tag contains the same nucleotide

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bases in sequence as the variant nucleotide and the invariant nucleotide of the target nucleic acid, as in claim 51.

### CONCLUSION


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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